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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,518	02/28/2006	Eduard Daniel Leendert Schmidt	294-208 PCT/US	2030

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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,518	SCHMIDT, EDUARD DANIEL LEENDERT	
	Examiner	Art Unit	
	STUART F. BAUM	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/7/2008 & 5/1/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/20/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The response to the election/restriction filed 4/7/2008 and the amendment filed 5/1/2008 have been entered.

2. Claims 19-27 are pending.

3. Applicant's election without traverse of Group I, claims 1-18, including the RKS4 gene in the reply filed on 4/7/2008 is acknowledged.

Claims 1-18 have been canceled.

Claims 19-27 have been newly added and are drawn to the elected invention.

4. Claims 19-27, including the RKS4 gene are examined in the present office action.

Specification

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See for example pages 6, 26, 45 and 94. See MPEP § 608.01.

Sequence Rules

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

Sequence identifiers are missing from pages, 29-43, 46-93 and 126-131.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules and a response to the issues set forth herein. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

Information Disclosure Statement

7. The information disclosure statement filed 4/20/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 19-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is indefinite in the recitation "RKS4 gene". The sole designation of a DNA sequence by "RKS4" is arbitrary and creates ambiguity in the claims. For example, the nucleic acid sequence in this application could be designated by some other arbitrary means, or the assignment of said name could be arbitrarily changed to designate a different nucleic acid

sequence. If either event occurs, one's ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F .2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). Amendment of the claim to refer to a specific SEQ ID NO would obviate this rejection.

Claim 27 is indefinite for reciting "a method for providing resistance to a plant or plant cell". It is unclear to what the plant is being resistant.

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 19-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for modulating a developmental pathway of a plant or plant cell or a method for providing resistance to a plant or plant cell comprising modifying a gene or modifying expression of said gene wherein said gene comprises an RKS4 gene or a functional equivalent thereof, or wherein the method is for modulating plant growth characteristics or meristem formation, size and identity, or vegetative organ formation, or reproductive organ formation, or organ size, or cell division, or pollen development.

Because of the 112 2nd rejection of claim 27 as discussed above, the Office interprets claim 27 to be drawn to a method of producing a plant or plant cell.

Applicant discloses the Arabidopsis thaliana RKS4 cDNA sequence (page 64-65).

The Applicant does not identify essential regions of any RKS4 protein, nor does Applicant describe a representative number of RKS4 sequences from a representative number of plants that all have the same activity/function.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicant fails to describe a representative number of polynucleotide sequences encoding a RKS4 protein. Applicant only describes a single cDNA sequence disclosed on pages 64-65 without an accompanying sequence identifier. Furthermore, Applicant fails to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicant fails to

meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the RKS4 protein, it remains unclear what features identify an Arabidopsis RKS4 protein. Since the genus of RKS4 proteins has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Enablement

10. Claims 19-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a method for modulating a developmental pathway of a plant or plant cell or a method for providing resistance to a plant or plant cell comprising modifying a gene or modifying expression of said gene wherein said gene comprises an RKS4 gene or a

functional equivalent thereof, or wherein the method is for modulating plant growth characteristics or meristem formation, size and identity, or vegetative organ formation, or reproductive organ formation, or organ size, or cell division, or pollen development.

Because of the 112 2nd rejection of claim 27 as discussed above, the Office interprets claim 27 to be drawn to a method of producing a plant or plant cell.

Applicant discloses the Arabidopsis thaliana RKS4 cDNA sequence (page 64-65).

Applicant has not reduced to practice the invention. Applicant has not disclosed a RKS4 nucleic acid sequence by sequence identifier that is modified or a plant in which the expression of said sequence is modified resulting in a plant comprising the claimed phenotypes. The state-of-the-art teaches transforming a plant with a protein kinase to modify or alter a particular phenotype leads to unpredictable results. Christensen et al (2000, Cell 100:469-478) teach that the PID nucleic acid encodes a plant-specific serine-threonine protein kinase and that said protein kinase regulates both the "mitogenic effects of auxin in the control of lateral meristem outgrowth and its morphogenic effects during embryogenesis and vascular patterning" (page 475, left column, 2nd paragraph). Therefore, overexpressing said nucleic acid produces multiple phenotypic effects that are not predictable.

Applicant has not disclosed how one makes or isolates any of the sequences that are encompassed by Applicant's broad claims. Applicant has not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences. Therefore, the instant specification fails to provide guidance for which amino acids of the protein encoded by the gene can be altered, the type of alteration, and which amino acids must not be changed, to maintain

activity of the encoded protein. The specification also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional protein.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of any gene as probes or by designing primers to undisclosed regions of any gene and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed produce a plant with the claimed phenotypes or modifying the gene by any undisclosed manner and then selecting a plant from the multitude that has all of the claimed phenotypes.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

If in fact the invention is enabled, then the following 102 rejection is set forth below.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 19-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al (1993, Development 119:397-418) taken with the evidence of Meyerowitz et al (1999, U.S. Patent Number 5,859,338).

The claims are drawn to a method for modulating a developmental pathway of a plant or plant cell or a method for providing resistance to a plant or plant cell comprising modifying a gene or modifying expression of said gene wherein said gene comprises an RKS4 gene or a functional equivalent thereof, or wherein the method is for modulating plant growth characteristics or meristem formation, size and identity, or vegetative organ formation, or reproductive organ formation, or organ size, or cell division, or pollen development.

Because of the 112 2nd rejection of claim 27 as discussed above, the Office interprets claim 27 to be drawn to a method of producing a plant or plant cell.

Clark et al disclose Arabidopsis clavata1 mutants that were generated by ethyl methanesulfonate (EMS) mutagenesis or X-ray induced mutatgenesis (page 398, right column, 1st full paragraph). The Office contends that because Applicants do not explicitly define a "RKS4 gene" as discussed in the 112 2nd rejection above, the Office interprets the recitation "RKS4 gene" to be drawn to any gene that when modified produces the same phenotype as what Applicant is claiming. In addition, Applicant defines "functionally equivalent" to mean genes that are not so homologous to RKS, or genes that are equivalent to RKS but encode a protein that comprises a deliberate modification such as a deletion, truncation, insertion, or an amino acid substitution made on the basis of similarity in polarity, charge solubility, hydrophobicity and/or the amphipathic nature of the residues as long as the biological activity of the polypeptide is retained (page 14, bottom paragraph). The Office contends based on Applicant's definition of RKS4 as discussed above, the CLAVATA1 protein is encompassed by Applicant's definition because it comprises a signal sequence, a leucine rich repeat domain, a single transmembrane domain and a serine/threonine protein kinase domain (See Meyerowitz et al., Figure 10; and page

65 of Applicant's specification). The mutant clavata1 gene produces a plant that has a modulation of plant growth characteristics, modulation of meristem formation, size and identity, modulation of vegetative organ formation, modulation of reproductive organs, modulation of organ size, modulation of cell division, modulation of pollen development (abstract, and result section) and as such, Clark et al taken with the evidence of Meyerowitz et al anticipate the claimed invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 19-27 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

This rejection is made because the claims as written, do not sufficiently distinguish over plants or plant cells as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *SeeDiamond v. Chakrabarty,* 447 U.S. 303, 206 USPQ 193 (1980). The Office contends modified genes occur in nature and the modification can alter expression levels.

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Stuart F. Baum/
Stuart F. Baum Ph.D.
Primary Examiner
Art Unit 1638
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